UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,641	11/30/1999	Danchen Gao	C-3169/1/US	9327

26648 7590 09/22/2006

PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/451,641	GAO ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-50,72-75,84 and 86-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,12-50,72-75,84 and 86-90* is/are rejected.

7)☐ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-10, 12-50, 72-75, 84 and 86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over AAPS Annual Meeting Contributed Papers Abstracts (AAPS), in view of Black EP 0 863 134, or Plachetka US 6,586,458, or Block et al. US 6,440,967.

AAPS teaches a celecoxib (Cox-2 inhibitor) formulation that exhibits a C_{max} value of 1527 and 1077 ng/mL, and a T_{max} of 1.9 hours (see page D32).

AAPS does not teach the use of excipients in the formulation. However, the use of excipients in oral formulations is well known in pharmaceutical art.

Black teaches a compound useful as a Cox-2 inhibitor for pain relief, fever and inflammation of a variety symptoms disclosed on page 3, lines 29-36. The compound can be administered orally in the form of tablets, troches, lozenges, or capsules (page 4, lines 1-12). The tablets comprise active ingredient in admixture with excipients, *e.g.*, diluents, disintegrants, binding agents, wetting agents, and surfactant (page 4, lines 15-38). The active agent is present in an amount of 10 to 250 mg. The carrier material may vary from about 5 to about 95% (page 5, lines 39-58). The dosage can be

administered once or twice a day, and will provide effective $T_{1/2}$ over a 24 hours period (page 5, lines 22-27). Example 2 discloses the amount of excipients use in a tablet.

Plachetka teaches a pharmaceutical composition comprising COX-2 inhibitor includes celecoxib (column 4, lines 8-9). Celecoxib can be formulated into tablet for once or twice per day in an amount of about 100 mg to 200 mg (column 6, lines 65 through column 7, lines 1-7). Plachetka also teaches the composition can be formulated into capsule, and other single dosage form with the use of excipients, such as filler, disintegrants, and wetting agents (column 10, lines 54-67).

Block teaches a pharmaceutical formulation comprising COX-2 inhibitor includes celecoxib (column 15, lines 11-12). The composition is formulated into solid dosage form such as powder, capsule, tablet or pill with the use of pharmaceutical carrier (column 18, lines 17-33; and examples 3-5). Block also teaches the amount of COX-2 is from 1-600 mg (column 22, lines 60-67).

Thus, it would have been obvious for one of ordinary skill in the art to modify the formulation of AAPS using the excipient/carrier in view of the teachings of Black, Plachetka, or Block to obtain the claimed invention, because the references teach oral dosage form of Cox-2 inhibitor including celecoxib that is useful in pharmaceutical art, and because AAPS teaches orally administering celecoxib in fine suspension and capsule forms having the claimed C_{max} and T_{max} values.

It is noted that AAPS does not expressly teach the particle size distribution, however, the burden is shifted to applicant to show that the formulation of AAPS does

not have the claimed particle size distribution, because AAPS teaches the oral formulation of celecoxib having the claimed C_{max} and T_{max} values.

Claims 1, 2, 4-10, 12-50, 72-75, 84 and 86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over AAPS Annual Meeting Contributed Papers Abstracts (AAPS), in view of Black EP 0 863 134 and Zhang et al. US 5,543,099.

AAPS and Black are relied upon for the reason stated above. It would have been obvious to one of ordinary skill in the art that the celecoxib formulation taught by AAPS would have the claimed particle distribution since AAPS teaches the same active agent in formulation that exhibits the same C_{max} and T_{max} values. However, to be more specific, Zhang is cited for the teaching that it is well known in the art to micronize active ingredient to obtain excellent content uniformity, consistent release profile, and good bioavailability (column 3, lines 8-17). Thus, it would have been obvious to one of ordinary skill in the art to modify the formulation of AAPS and Black to micronize the active agent, namely celecoxib in view of the teaching of Zhang to obtain the claimed invention, because Zhang teaches active granule having excellent content uniformity, because Zhang teaches granule having the claimed particle size, *e.g.*, from 0.1 to 50 micrometers (column 3, lines 53-55), and because Zhang teaches micronizing active agent having similar property as the claimed celecoxib, such as highly water-insoluble (column 3, lines 25-29).

Response to Arguments

Applicant's arguments filed 07/12/06 have been fully considered but they are not persuasive.

Applicant argues that given the special disadvantageous properties of celecoxib it is, in fact, only by employing a particular milling techniques as disclosed from the patent specification, that the problems associated with the cohesive nature of celecoxib can be overcome, *i.e.*, that a uniformly blended composition with the particle size distribution according to claim 1 may be obtained. However, in response to applicant's argument, assuming that it would not have been obvious to one of ordinary skill in the art to select the particular particle size distribution, the unexpected results over the uniformly blended composition with the particle size distribution according to claim 1 have not been shown. Applicant's attention is called the to teaching of the same properties being claimed, that is the AAPS teaches orally administering celecoxib in capsule form having the claimed C_{max} and T_{max} values. Furthermore, independent claim 1 does not even recite a particular excipient in any specific amount that would result in the claimed properties, *e.g.*, the bioavailability of not less than about 50%, and the C_{max} and T_{max} values. Accordingly, the examiner is unable to determine the unexpected and/or unusual results over the AAPS reference. Much less, does the composition function the way it claimed with any excipients, and in any amounts?

Claims Allowable

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Primary Examiner
Art Unit 1615